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| 10/816,677 | 04/02/2004 | Kinh-Luan (Lenny) Dao | 03-302 | 9708 |

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| EXAMINER | |
|---|---|
| GHALI, ISIS A D | |

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| 1611 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/816,677 | DAO ET AL. | |
| | Examiner | Art Unit | |
| | Isis A. Ghali | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *2-4,6-8,12-15,20,21,24,25,27-30 and 33-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,9-11,16-19,22,23,26,31,32 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/11/2005; 10/12/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The receipt is acknowledged of applicants' IDS filed 03/11/2005; IDS filed 10/12/2006; and election filed 12/03/2007.

Claims 1-42 are pending.

### *Election/Restrictions*

1. Applicant's election with traverse of species: solvent assisted adhesive, medical article comprising microparticles, microspheres, biostable microparticles, therapeutic agent admixed in powder form with microparticles, therapeutic agent adhered to the adhesive region, medical article comprising adhesive and therapeutic agent, and stent, claims 1, 5, 9-11, 16-19, 22, 23, 26, 31, 32, 39-42 in the reply filed on 12/03/2007 is acknowledged. The traversal is on the ground(s) that the species are not mutually exclusive and overlapping in scope. This is not found persuasive because claims to the different species recite the mutually exclusive characteristics of such species, in addition, these species are not obvious variants of each other based on the current record. There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The Species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would

not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2-4, 6-8, 12-15, 20, 21, 24, 25, 27-30, 33-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/03/2007.

Claims 1, 5, 9-11, 16-19, 22, 23, 26, 31, 32, 39-42 are included in the prosecution.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 5, 9, 10, 16-19, 22, 23, 26, 40, and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0100830 ('830).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '830 disclosed an implantable or insertable medical device coated at least partially with polymer (abstract; paragraph 0014). The polymer coating includes polyacrylate and acrylic acid polymers (paragraphs 0021, 0029) that are disclosed by applicants at paragraph 0023 as suitable adhesives. The polymer is biodegradable (paragraph 0023). The device comprises therapeutic agent on the surface of the polymeric material soaking or dipping the coated device in solution of the therapeutic agent followed by drying, i.e. not spray dried microparticles (paragraph 0069). The device is further coated with small magnetic particles, which read on biostable microparticles (paragraph 0061-0062). The polymer is coated on the surface of the device from a solution, followed by drying, i.e. solvent assisted (paragraphs 0046, 0059, 0069). The medical device is a stent (paragraph 0068).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being obvious over US '830.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer

in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of US '830 are previously discussed as set forth in section 4 of this office action.

Although US '830 teaches small magnetic particles, however, the reference does not explicitly teach the particle size as instantly claimed by claim 11.

Applicants failed to show unexpected results obtained from the claimed particle diameters, therefore, it would have been obvious to one having ordinary skill in the ad at the time the invention was made to have particles on the adhesive layer covering medical devices with a diameter between 0.1 to 50 μm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges and dimensions involves only routine skill in the art. *In re Aller* 105 USPQ 233.

8. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being obvious over US '830 in view of US 6,592,895 ('895).

The applied reference (US '830) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is

thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of US '830 are previously discussed as set forth in section 4 of this office action.

Although US '830 teaches therapeutic agents coated on the polymer layer covering the medical device, however, the reference does not explicitly teach the high molecular weight therapeutic agents as instantly claimed by claims 31 and 32.

US '895 teaches that therapeutic agents having large molecules such as nucleotides can be delivered from a coating applied to a stent and released to the site of application (abstract; col.6, lines 50-54; col.7, lines 30-35, 43-47; col.8, lines 5-9).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical device such as stent covered with polymer coated with therapeutic agent and microparticles as disclosed by US '830, and replace the therapeutic agent with high molecular weight nucleotides as disclosed by US '895 because US '895 teaches that nucleotides can be delivered from a coating on a stent at

the application site, with reasonable expectation of having stent covered with polymer coated with nucleotides and microparticles that delivers the nucleotides successfully at the application site to patients in need of such treatment.

9. Claims 39 and 42 are rejected under 35 U.S.C. 103(a) as being obvious over US '830 in view of US 6,545,097 ('097).

The applied reference (US '830) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of US '830 are previously discussed as set forth in section 4 of this office action.

Although US '830 teaches therapeutic agents coated on the polymer layer covering the medical device, however, the reference does not teach covering the therapeutic agent by disintegrable layer as instantly claimed by claimed 39 and 42.

US '097 teaches implantable device such as stent covered with biocompatible degradable polymer comprising therapeutic agent and covered with sheath to prevent premature therapeutic agent release (abstract; col.5, lines 19-23; col.14, lines 20-26).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical device such as stent covered with polymer coated with therapeutic agent and microparticles as disclosed by US '830, and further provide biocompatible degradable polymer covering over the therapeutic agents and the microparticles as disclosed by US '097 because US '097 teaches that such covering prevents premature therapeutic agent release, with reasonable expectation of having stent covered with polymer coated with therapeutic agent and microparticles and further covered with biocompatible degradable polymer covering wherein premature release of the therapeutic agents is successfully prevented.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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